

## REMARKS

Reconsideration and allowance of the present application are respectfully requested.

Claims 1, 2, 7, 8, 11, 12, 15, and 17 are pending in the application.

Claims 1 and 2 have been amended to incorporate the subject matter of dependent claims 4-6. Claims 1 and 2 have been amended to replace the term "active centre species" with "cyclic structures and acetals," support for which can be found in the originally filed application including at page 2, lines 10-11. No new matter has been added.

The undersigned thanks Examiner Allen for the courtesy extended during the telephone interview of 2 August 2007. The claim amendments set forth above were discussed during the interview.

The rejection of claims 1-20 under 35 U.S.C. § 112, first paragraph, on pages 2-3 of the Final Office Action, is obviated by the amendment to claims 1 and 2 as set forth above. The step of treating the cross-linking agent with the purifying agent now is recited before the step of immobilizing the enzyme. The term "aldehyde cross-linking agent" has been replaced with "glutaraldehyde cross-linking agent." No new matter has been added.

Applicants respectfully submit that the claimed invention fully complies with Section 112, first paragraph. Accordingly, withdrawal of the Section 112, first paragraph, rejection is respectfully requested.

The rejection of claims 1-20 under 35 U.S.C. § 112, first and second paragraph, on pages 3-4 of the Office Action, is obviated by the amendment to claims 1 and 2 as set forth above. The term "active centre species" has been replaced with "cyclic structures and acetals." Applicants respectfully submit that claims 1-20 fully comply with Section 112, first and second paragraphs. Accordingly, withdrawal of the Section 112 rejections is respectfully requested.

Present claims 1, 2, 7, 8, 11, 12, 15, and 17 are not anticipated by U.S. Patent No. 4,369,226 (Rembaum).

In Example 1, Rembaum teaches that commercial glutaraldehyde solutions can be treated with activated carbon yielding a solution free of polymeric species.

Rembaum then proceeds to take this purified glualdehyde solution, and create polymer by base catalysis, leading to **polymeric** glutaraldehyde with a MW of ~20 kDa.

Rembaum uses this polymerized glutaraldehyde in all subsequent examples, stating that the polymerized glualdehyde is better suited to covalent binding of various proteins, and leads to a faster reaction time (Figures 2 and 3). Ultimately, Rembaum states "[t]he high reactivity of polyglutaraldehyde, its stability, ease of administration, and the retention of human immunoglobulins bound to the polymer, makes it a desirable new reagent for protein binding".

Furthermore, the summary of invention section in Rembaum states that "[i]n contrast to monomeric glutaraldehyde, the **polymer** contains conjugated aldehyde groups. This imparts stability to the Schiff's bases formed after reaction with proteins, and, further, since the hydrophilic polyglutaraldehyde has relatively long chains extending from the surface into the surrounding aqueous medium, the heterogeneous reaction with protein is facilitated." (Emphasis added.)

Thus, although Rembaum discloses the use of activated carbon to remove polymeric species from glutaraldehyde solutions, Rembaum does not teach using glutaraldehyde for immobilization. Rather, Rembaum teaches to use a **polymeric** form of glualdehyde for protein immobilization. This is in direct contrast to Applicants' approach, findings and teachings.

Applicants' results, indeed, show that use of activated carbon can remove polymeric aldehyde species (such as Rembaums' polymeric glutaraldehyde), cyclic structures and acetals.

Rembaum subsequently treated this purified solution with base to create polymeric forms of glutaraldehyde for immobilization. In contrast, Applicants use the purified glutaraldehyde solution, with a lower polyaldehyde content, to effect immobilization, and, indeed, found that in instant process, using a glutaraldehyde solution with greater monomeric content provided superior protein immobilization.

Applicants' use of a glutaraldehyde solution with a greater monomeric content is, thus, in direct contrast to the procedure and teachings of Rembaum. Rembaum explicitly prepared and used polymeric glutaraldehyde, because Rembaum believed

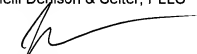
U.S. Serial No. 10/797,020  
2 August 2007  
Page 7

that polymeric glutaraldehyde was superior to the monomeric form. For these reasons, Rembaum, in fact, not only does not disclose present process but leads away from the presently claimed process.

In light of all of the objections and rejections of record having been addressed, Applicants submit that the claimed invention is in condition for allowance and Notice to that affect is respectfully requested.

Respectfully submitted,  
Manelli Denison & Selter, PLLC

By



Jeffrey S. Melcher  
Reg. No.: 35,950  
Tel. No.: 202.261.1045  
Fax. No.: 202.887.0336

Customer No. 20736  
2000 M Street, N.W. , 7<sup>th</sup> Floor  
Washington, D.C. 20036-3307